K122275

SECTION 7

AUG 2 9 2012

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Applicant Information:

Owner Name: Hansen Medical, Inc.
Address: 800 East Middlefield Road
Mountain View, CA. 94043
Office: 650-404-5800

Contact Person: Hassan Labay
Phone Number: 650 404 5888
Facsimile Number: 650 404 2773

Date Prepared: 7/25/2012

Device Information:

Classification: Class II
Trade Name: Artisan® Extend Control Catheter
Common name: Steerable Guide Catheter
Classification name: Catheter, Steerable, (21 CFR 870.1280 / DRA)

Predicate Devices:

The Hansen Medical Artisan Extend Control Catheter is substantially equivalent in intended use and method of operation to the Hansen Medical Steerable Guide Catheter (SGC) and Sheath ("Artisan® Control Catheter") (K073225).

Device Description:

The Hansen Medical Artisan Extend Control Catheter is designed to facilitate manipulation, positioning and control of mapping percutaneous catheters within the atria of the heart. The Artisan Extend Control Catheter consists of a Steerable Guide Catheter (SGC) and Sheath. The Control Catheter is designed to be used with the Hansen Medical Sensei® X Robotic Catheter System.

Intended Use:

The Hansen Medical Artisan Extend Control Catheter is intended to facilitate manipulation, positioning and control, for collecting electrophysiological data within the heart atria with electro-anatomic mapping and recording systems, using the following percutaneous mapping catheters: the Polaris-Dx™ Steerable Diagnostic catheters made by Boston Scientific Corporation and the Livewire™ Electrophysiology catheters made by St. Jude Medical.

The Artisan Extend Control Catheter is intended to be used with the Hansen Medical Sensei® X Robotic Catheter System.

Comparison to Predicate Device(s):

The Hansen Medical Artisan Extend Control Catheter consists of a simplified proximal flush assembly when compared to Artisan Control Catheter's flush assembly. The modifications described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device.

Technological Characteristics/Performance Data:

The Artisan Extend Control Catheter is substantially equivalent to the predicate device in intended use, fundamental scientific technology, and performance specifications. Design verification testing was performed to verify that the performance of the Artisan Extend Control Catheter remains substantially equivalent to the predicate device. The catheter has been tested for biocompatibility according to ISO10993-1 and was determined to be biocompatible. Testing performed on the Artisan Extend Control Catheter included the following:

- Pressure Leak Test
- Vacuum Test
- Tensile Strength Test
- Flush Test
- Compatibility with Sensei X Test
- Biocompatibility Testing
  - ISO MEM Elution Cytotoxicity Test
  - ISO Kligman Maximization Test
  - ISO Intracutaneous Reactivity Study
  - ISO Acute Systemic Toxicity Study
  - ASTM Hemolysis
  - ISO Thrombogenicity Study
  - ISO Complement Activation Assay

All of the pre-determined acceptance criteria were met with passing results.

Clinical Testing:

Clinical evaluation was not required for this device.

Substantial equivalence:

The Artisan Extend Control Catheter with the modified proximal flush assembly has the following similarities to the predicate device which previously received clearance under K073225.

- has the same indication for use,
- has the same fundamental scientific technology,
- incorporate the same basic catheter design,
- incorporate the same materials,
- has the same shelf life, and
- is sterilized using the same sterilization processes.

In summary, the Artisan Extend Control Catheter subject to this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 29 2012

Hansen Medical Inc.
c/o Mr. Hassan Labay
Senior Regulatory Affairs Associate
800 East Middlefield Road
Muntain View, CA 94043

Re: K122275
Trade/Device Name: Artisan Extend Control Catheter
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter.
Regulatory Class: Class II (two)
Product Code: DRA
Dated: July 25, 2012
Received: July 30, 2012

Dear Mr. Labay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Hansen Medical Artisan® Extend Control Catheter

Indications for Use:

The Hansen Medical Artisan Extend Control Catheter is intended to facilitate manipulation, positioning and control, for collecting electrophysiological data within the heart atria with electro-anatomic mapping and recording systems, using the following percutaneous mapping catheters: the Polaris-Dx™ Steerable Diagnostic catheters made by Boston Scientific Corporation and the Livewire™ Electrophysiology catheters made by St. Jude Medical.

The Artisan Extend Control Catheter is intended to be used with the Hansen Medical Sensei® X Robotic Catheter System.

Prescription Use _x_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122275